

Appln. No.: 10/760,129

BSI-566US

Appeal Brief Dated: August 21, 2007



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No: 10/760,129
Appellant: Peter S. Brown et al.
Filed: January 16, 2004
Title: ENDOVASCULAR GRAFT WITH PRESSOR AND ATTACHMENT METHODS
T.C./A.U.: 3738
Examiner: Cheryl L. Miller
Confirmation No.: 7202
Docket No.: BSI-566US

APPEAL BRIEF

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby request consideration and reversal of the Final Rejection dated December 22, 2006, and the Advisory Action dated March 2, 2007, of claims 1, 2, 4, 7, 8 and 28-33.

This Brief is presented in the format required by 37 C.F.R. § 41.37, in order to facilitate review by the Board. In compliance with 37 C.F.R. § 41.37(a)(1), this Brief is being filed within the time allowed for response to the action from which the Appeal was taken or within two months from the date of the Notice of Appeal, whichever is later.

The fees for filing a Brief in support of an Appeal under 37 C.F.R. § 41.20(b)(2), together with any extension fee required in connection with the filing of this Brief, are provided herewith.

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I. REAL PARTY IN INTEREST

The real party in interest is Endovascular Technologies, Inc., the assignee of record, which is a subsidiary of Boston Scientific Corporation.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 3, 5, 6 and 9-27 are cancelled.

Claims 1, 2, 4, 7, 8 and 28-33 are pending and stand finally rejected.
Claims 1, 2, 4, 7, 8 and 28-33 are on appeal.

IV. STATUS OF AMENDMENTS

An amendment subsequent to the Final Rejection was filed on February 21, 2007. That amendment has been entered for purposes of appeal.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention relates to a method of protecting a sensor and a marker attached to a graft intended to be delivered within vasculature using a catheter. This aspect of the invention is described in the specification, *inter alia*, at page 18, line 25 through page 19, line 24 and with reference to FIGS. 7 - 13.

"With reference to FIGS. 7 and 8, there is shown a typical medical device in the form of a graft 200 for use in interventional procedures such as aortic aneurysm repair. For any of the previously discussed reasons, the graft 200 can be equipped with a sensing or other device 210. Radiopaque markers 212 can also be attached to the graft as well as stents 214 or other frames or anchoring devices. In a situation where there is an interest in protecting the sensing device 210 during advancement of the graft 200 to an interventional site, using a delivery catheter 216, the graft 200 can be initially folded in a generally H-shaped configuration, such that the sensor 210 is placed between a pair of folds 220, 222 in the graft 200. As the delivery catheter 216 is drawn over the graft 200 and sensor 210, the graft itself acts as a protection barrier.

Various approaches can be taken to protect a sensing device 210. For example, as shown in FIGS. 9 and 11, after folding the graft into an H-configuration, a second fold 232 is placed in legs 234 of the H-shape. Where a membrane 240 of a sensor 210 is oriented generally perpendicularly to a radius 250 of the tubular graft device 210 (See FIGS. 9 and 10), one folded leg 234 is placed over the membrane 240 thereby providing a double layer of protection for the sensor 210 when placed within a delivery catheter 216. Alternatively, as shown in FIGS. 11 and 12, where the sensor membrane 240 is generally parallel to a graft radius, folded portions 252 of two legs 234 can be configured over the sensor 210 for protection where the graft 200 is loaded within a catheter 216.

In either approach, the fragile membrane 240 of a sensor 210 is protected from trauma and wear during loading within a catheter 216 as well as advancement within vasculature. Moreover, the sometimes fragile membrane 240 is therefore only exposed upon deployment at an interventional site. Such an approach can ensure that the sensor is fully operational when implanted at an interventional site.

In a related approach (See FIG. 13), instead of using two folded sections to protect a sensor or otherwise placing a second fold 232 within a leg 234, a leg 232 can be directly placed over a sensor for protection. Other folding approaches can also be employed for protection."

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claim 2 is unpatentable under 35 U.S.C. §112, first paragraph, for lack of enablement?

B. Whether claims 1, 2, 4, 7, 8, 28-30 and 33 are unpatentable under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,840,956 (Wolinsky).

C. Whether claims 1, 2, 4, 7, 8 and 28-33 are unpatentable under 35 U.S.C § 103(a) as unpatentable over Wolinsky in view of U.S. Patent No. 5,749,920 ("Quiachon").

VII. ARGUMENT

A. Rejection Of Claim 2 Under 35 U.S.C. §112, First Paragraph

Claim 2 stands rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. Appellants respectfully submit that claim 2 is enabled by the specification.

35 U.S.C. 112 states in pertinent part, that:

[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 recites "The method of claim 1, further comprising configuring the graft to define an H-shape." The specification clearly explains at page 18, line 25 through page 19, line 24 and illustrates in Figures 7-13, how the graft is initially positioned in an H-shape and thereafter portions are folded to cover the sensors and markers. Such description would clearly enable any person skilled in the art to use the claimed invention. The Advisory Action speculates that the claim may be read broader to cover other procedures, however, the specification is not required to explain every possible use of the method. The specification does as required under 35 U.S.C. §112, first paragraph, and describes the invention in such a clear manner as to enable any person skilled in the art to use the claimed invention.

Appellants respectfully request reconsideration and reversal of the rejection of claim 2 under 35 U.S.C. §112, first paragraph.

B. Rejection Under 35 U.S.C. §102(e) Over U.S. Patent No. 6,840,956

Claims 1, 2, 4, 7, 8, 28-30 and 33 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,840,956 (Wolinsky). It is respectfully submitted, however, that the pending claims are patentable over the art of record for at least the reasons set forth below.

Anticipation requires that each and every limitation of the claim be disclosed, either expressly or under principles of inherency, in a single prior art reference. *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Absence from the reference of any claimed limitation negates anticipation. *Rowe v. Dror*, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

Independent claim 1 recites:

"A method of protecting a sensor attached to a graft intended to be delivered within vasculature using a catheter, comprising:

attaching a sensor to a graft;

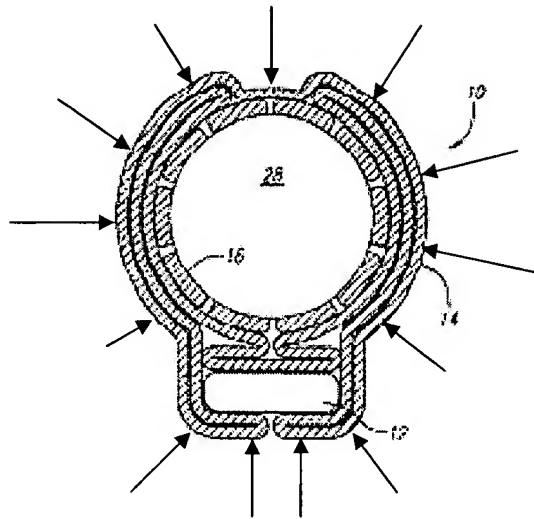
attaching a marker to the graft;

folding portions of the graft to cover the sensor and the marker; and

placing the graft within a catheter."

The Office Action states that Wolinsky discloses the use of markers on an implant at Column 6, lines 13-16. The Office Action acknowledges that Wolinsky does not show such a feature in the reference. To support the anticipation rejection, the Office Action concludes, "inherently the markers will be covered, since they are present on a graft surface and as the entire graft is seen folded over itself, inherently it will cover the markers, wherever they are on the graft, see Fig. 3A." (Office Action, page 3). The Office repeated this position in the Advisory Action dated March 2, 2007, stating that Wolinsky "clearly" discloses folding of the "entire graft" along with the use of markers on the graft. Specifically in the Advisory Action, the Office states the position that "since the markers are placed on the graft and since the graft is folded, the markers are folded over with the graft folding." (Advisory Action, page 2).

Figure 3A of Wolinsky, which is relied on in the Office Action and the Advisory Action, is reproduced below. The arrows inserted by Appellants in the Figure 3A illustrate only a few exemplary positions along the graft wherein the markers may be placed without being covered by the graft, even when folded.



The arrows above make it clear that it is not inherent that the markers of Wolinsky are covered by the folded over graft. To the contrary, a significant large area of the graft, even in the folded condition, remains uncovered. The Office Action does not provide any further support for Wolinsky disclosing that the markers, mentioned only in passing, are covered by folded portions of the graft.

Since Wolinsky does not disclose every limitation of the claimed invention, the claimed invention is not anticipated thereby. Appellants respectfully request reconsideration and reversal of the rejection of claims 1, 2, 4, 7, 8 and 28-30 and 33 under 35 U.S.C. §102(e).

C. Rejection Under 35 U.S.C. §103(a) Over U.S. Patent No. 6,840,956 in View of U.S. Patent No. 5,749,920

Claims 1, 2, 4, 7, 8 and 28-33 stand rejected under 35 U.S.C § 103(a) as unpatentable over Wolinsky in view of U.S. Patent No. 5,749,920 ("Quiachon"). It is respectfully submitted, however, that the pending claims are patentable over the art of record for at least the reasons set forth below.

"To establish a *prima facie* case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §2143. Additionally, as set forth by the Supreme Court in KSR Int'l Co. v. Teleflex, Inc., No. 04-1350 (U.S. Apr. 30, 2007), it is necessary to identify a reason

that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the manner claimed.

Independent claim 1 recites:

"A method of protecting a sensor attached to a graft intended to be delivered within vasculature using a catheter, comprising:

attaching a sensor to a graft;

attaching a marker to the graft;

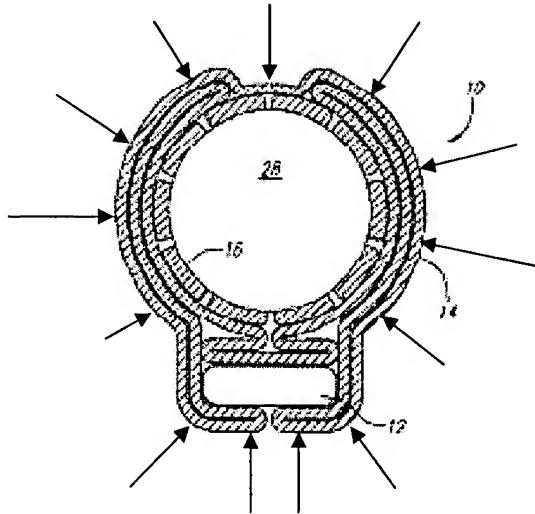
folding portions of the graft to cover the sensor and the marker; and

placing the graft within a catheter."

The Office Action states that Wolinsky discloses the use of markers on an implant at Column 6, lines 13-16. The Office Action acknowledges that Wolinsky does not show such a feature in the reference. To support the obviousness rejection, the Office Action states "Quichon teaches in the same field of vascular grafts, placement of a plurality of markers (197; fig.23) along the length of the graft (55) such that the graft may be detected during deployment (col.14, lines 18-29). (Office Action, page 4). The Office Action concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to combine Wolinsky's alleged teaching of a graft having radiopaque markers with Quichon's teaching of "exact placement of the marker directly onto the graft surface such that the graft may be detected during delivery." (Office Action, page 5). The Office Action further asserts that Wolinsky's graft will fold over the markers as well as the sensor, since the entire graft is folded upon itself. The Office repeated this position in the Advisory Action dated March 2, 2007, stating that Wolinsky "clearly" discloses folding of the "entire graft" along with the use of markers on the graft. Specifically in the Advisory Action, the Office states the position that "since the markers are placed on the graft and since the graft is folded, the markers are folded over with the graft folding." (Advisory Action, page 2).

Again, the Office Action indicates that the covering of the markers would be inherent. As pointed out above, and illustrated again below, the arrows make it

clear that it is not inherent that the markers of Wolinsky are covered by the folded over graft.



The Office Action does not provide any further support for Wolinsky disclosing that the markers, even those disclosed by Quichon, are covered by folded portions of the graft. In fact, Quichon teaches away from the markers being positioned along an area that may be folded or otherwise folded over. Quichon explains at column 14, lines 46-53, that "[b]y placing markers of different lengths along the axis of the tubular member, it is possible to ascertain the position of the graft 55 and to determine whether the graft has twisted between its superior and inferior ends 171, 172. Under fluoroscopy, the two sets markers will be exhibited as two relatively straight lines for an untwisted graft, wherein a twisted graft will be revealed by a non-linear pattern of markers." (emphasis added). To position the markers at a position where they may be folded over or folded upon, may twist the markers and prevent the markers from being used to determine whether the graft has twisted. Quichon teaches against the combination proposed in the Office Action.

Since Wolinsky and Quichon, even if combined, do not disclose every limitation of the claimed invention, but instead teach away from the claimed invention, a *prima facie* case of obviousness has not been established. Appellants

respectfully request reconsideration and reversal of the rejection of claims 1, 2, 4, 7, 8 and 28-33 under 35 U.S.C. §103(a).

Accordingly, for at least the above reasons, appellants respectfully contend that independent claim1 and dependent claims 2, 4, 7, 8 and 28-33 of this application are now in condition for allowance. Accordingly, appellants respectfully request reversal of the Final Rejection.

Respectfully Submitted,

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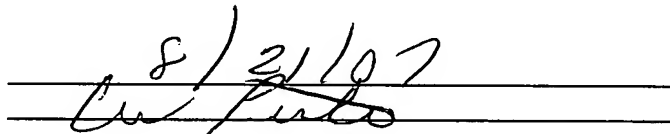
Enclosures: Claims Appendix
Evidence Appendix
Deleted Proceedings Appendix

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APPENDIX OF CLAIMS

1. A method of protecting a sensor attached to a graft intended to be delivered within vasculature using a catheter, comprising:
 - attaching a sensor to a graft;
 - attaching a marker to the graft;
 - folding portions of the graft to cover the sensor and the marker; and
 - placing the graft within a catheter.
2. The method of claim 1, further comprising configuring the graft to define an H-shape.
3. (Canceled)
4. The method of claim 1, further comprising folding more than two layers of graft material over the sensor.
5. (Canceled)
6. (Canceled)
7. The method of claim 1, further comprising placing a double-folded section of graft material over the sensor.
8. The method of claim 1, further comprising placing a single folded section of graft material over the sensor.
9. - 27. (Canceled)
28. The method of claim 1, further comprising configuring a membrane of the sensor so that the membrane is substantially perpendicular to a radius of an unfolded graft.
29. The method of claim 1, wherein different portions of the graft are used to cover the sensor and the marker.

30. The method of claim 1, wherein a plurality of markers are attached to the graft.
31. The method of claim 30, wherein the plurality of markers are positioned laterally spaced from the sensor.
32. The method of claim 31, wherein each of the plurality of markers are covered by portions of the graft.
33. The method of claim 1, wherein four layers of the graft are folded over the sensor.

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EVIDENCE APPENDIX

None

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RELATED PROCEEDINGS APPENDIX

None